










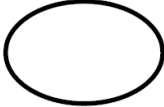























Symbol	Description of symbol	Reference number and title of symbol
ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements		
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1 Manufacturer
	Indicates the authorized representative in the European Community.	5.1.2 Authorized representative in the European Community/European Union
	Indicates the date when the medical device was manufactured.	5.1.3 Date of Manufacture
	Indicates the date after which the medical device is not to be used.	5.1.4 Use-by date
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5 Batch code
	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6 Catalogue number
	Indicates the manufacturer's serial number so that a specific medical device can be identified.	5.1.7 Serial number
	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3 Sterilized using ethylene oxide
	Indicates a medical device that has been sterilized using irradiation.	5.2.4 Sterilized using irradiation

Symbol	Description of symbol	Reference number and title of symbol
	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8 Do not use if package is damaged
	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	5.2.9 Sterile fluid path
	Indicates a single sterile barrier system	5.2.11 Single sterile barrier system
	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1 Fragile, handle with care
	Indicates a medical device that needs protection from light sources.	5.3.2 Keep away from sunlight
	Indicates a medical device that needs to be protected from moisture	5.3.4 Keep dry
	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7 Temperature limit
	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8 Humidity limitation

Symbol	Description of symbol	Reference number and title of symbol
	Indicates a medical device that is intended for one single use only	5.4.2 Do not re-use
	Indicates the need for the user to consult the instructions for use.	5.4.3 Consult instructions for use or consult electronic instructions for use
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	5.4.4 Caution
	Indicates a medical device that is non-pyrogenic.	5.6.3 Non-pyrogenic
	Indicates the number of drops per milliliter.	5.6.4 Drops per milliliter
	Indicates the item is a medical device	5.7.7 Medical device
ISO 7000 Graphical symbols for use on equipment - Registered symbols		
	To indicate that hooks shall not be used for handling the transport package.	0622 Use no hooks
	To indicate correct upright position of the transport package	0623 This way up
	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.	2402 Do not stack

Symbol	Description of symbol	Reference number and title of symbol
	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.	2403 Stacking limit by number
	To indicate that the transport package shall not be rolled or turned over but shall remain in the upright position.	2405 Do not roll
Symbols <u>not</u> from Standards		
Rx Only or R ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	FDA Quality System Regulation – Labeling requirements 21 CFR Part 801.109: Prescription use only
	Not made with natural rubber latex	NA
	Not made with di(2-ethylhexyl) phthalate	NA
	Not made with Bisphenol-A	NA
	Not for use with Hemodiafiltration	NA
	This device must be used on dialysis machines with an ultrafiltration controller or accurate fluid balancing system.	NA